

### **Remarks**

Claims 1-11 are pending. Claims 1-11 are rejected.

#### **Claim Rejections - 35 U.S.C. § 112 - 1st Paragraph**

Claims 1-10 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

The generic chemical formulae containing the "m and "n" parameters has been deleted from claim 1. The amendment of claim 1 overcomes the present rejection. Accordingly, for at least these reasons, claims 1-10 are allowable under 35 U.S.C. § 112, first paragraph.

#### **Claim Rejections - 35 U.S.C. § 112 - 2nd Paragraph**

Claims 1-10 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Applicant has amended claim 1 to a liquid comprising a fluorinated ether. The Specification provides three options for the formulations according to the invention containing a different fluorinated ether (i.e., HFE750, HFE7200 and HFE7100) thereby providing a sufficient number of representative species to justify the scope of amended claim 1.

Accordingly, for at least these reasons, claims 1-10 are allowable under 35 U.S.C. § 112, second paragraph

#### **Claim Rejections - 35 U.S.C. § 103**

Claims 1-11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Roser, J.R. in US Patent 6,190,701 (published: 02/20/2001) in view of Johnson, K.A. in US Patent 5,376,359 (published: 12/27/1994) and Owens, J.G., in Low GWP Alternatives to HFCs and PFCs, Report of 3M Company Specialty Materials, St. Paul, MN, USA (2000).

Claim 1 as amended is directed to a formulation comprising an active ingredient preserved in glassy or amorphous particles. The particles are suspended in a liquid in which at least one component comprises a fluorinated ether.

The benefits of using a fluorinated ether in the formulations relative to the use of a perfluorocarbon are outlined at page 3, lines 1-12 and page 4, lines 7-16 of the Specification. These include the facile dispersion of a glass particle/active ingredient mixture into a milky suspension with little or no clumping as observed for perfluorocarbons and which is maintained over a period of time. This effect is believed to be evident because glass particles have hydrophilic surfaces, whereas perfluorocarbons are believed to be intensely hydrophobic.

Furthermore, additional benefits are that fluorinated ethers are considered less environmentally damaging than perfluorocarbons. Moreover, fluorinated ethers are more readily obtainable in higher purity than perfluorocarbons, and less costly to purchase.

The Examiner has raised obviousness rejections against the pending claims based on the disclosures of Roser (U.S. 6,190,701 B1), Johnson (U.S. 5,376,359), and Owens (Report of 3M Company Specialty Materials). In summary, these references disclose the following.

Roser discloses compositions for delivering a stable, bioactive compound to a subject which comprises a first component being a glass-containing bioactive agent and a second component, which is at least one biocompatible perfluorocarbon. There is no disclosure in Roser of another class of fluorine-containing organic compounds (e.g., fluorinated ethers as in amended claim 1), which may be employed in place of a perfluorocarbon.

Johnson discloses stabilized aerosol drug formulations which are prepared by

combining a solid particulate drug composition with a (solid) fluoropolymer in a liquid fluorocarbon aerosol propellant to form a liquid suspension. Examples of the fluorocarbon aerosol propellant include fluorinated ethers (refer to column 2, lines 58-63). Hydrofluoroalkanes are preferred (refer to column 2, line 68 to column 3, line 3).

Owens provides an overview of hydrofluoroethers which focuses on their atmospheric lifetimes and hence their suitability as alternatives to other fluorine-containing organic compounds with ozone-depleting properties. Owens states that segregated hydrofluoroethers can be useful replacements for other fluorinated organic compounds in a range of industrial applications. These applications include as solvents in cleaning and coating deposition processes, as well as in heat transfer fluids such as refrigerants. There is no disclosure in Owens of the biological applications of hydrofluoroethers or the role of hydrofluoroethers may have in the effective dispersion of solid particles in bioactive formulations.

With respect to the perfluorocarbon-containing formulations of Roser, Applicant submits that there is no teaching or suggestion either within Roser, Johnson, or Owens for the person skilled in the art to modify the perfluorocarbon-containing formulations of Roser to include a fluorinated ether and thus arrive at a formulation according to the present invention with improved dispersion properties. This analysis is evident since Roser states that the use of a perfluorocarbon provides suitable properties relating to dispersion permitting the formation of stable suspensions (refer to column 5, lines 46-58). Therefore, there was no motivation for the skilled person to modify the teaching of Roser by referring to the disclosure of the use of fluorinated ethers in the non-glass containing formulations disclosed in Johnson or the general overview of the environmentally-friendly nature of hydrofluoroethers as discussed in Owens.

Notwithstanding the analysis set forth above, the references taken as a whole do not provide a suggestion or teaching that the use of a fluorinated ether would have lead to the superior dispersion properties observed for these compounds over the perfluorocarbons employed in the formulations of Roser. This is because Johnson is silent with respect to the dispersion properties of the fluorinated ethers identified at column 2, lines 58-63. Furthermore, Owens provides no teaching that the hydrofluoroethers disclosed therein would provide the beneficial

dispersion properties observed in the present invention. For these reasons, the formulations of amended claim 1 are non-obvious over the cited prior art.

Since claims 2-11 depend from claim 1, these claims are also allowable.

Accordingly, for at least these reasons, claims 1-11 are allowable under 35 U.S.C. § 103(a) over Roser in view of Johnson and Owens.

### **Double Patenting**

Claims 1-6 and 10-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-4, 13, and 16-18 of Roser in U.S. Patent 6,190,701, in view of Johnson in U.S. Patent 5,376,359.

As the claims have been amended to render them patentably distinct over the claims of the Roser reference in light of Johnson, the double patenting objection is now moot.

### **Conclusion**

Applicant has made a genuine effort to respond to each of the Examiner's objections and rejections in advancing the prosecution of this case. Applicant believes that all formal and substantive requirements for patentability have been met and that this case is in condition for allowance, which action is respectfully requested. If any additional issues need to be resolved, the Examiner is invited to contact the undersigned at his earliest convenience.

S/N: 10/599,928  
Reply to Office Action of March 3, 2009

Atty Dkt No. ROUS 0101 PUSA (formerly TOPT 0103 PUSA)

The Petition fee of \$555.00 is being charged to Deposit Account No. 02-3978 via electronic authorization submitted concurrently herewith. The Commissioner is hereby authorized to charge any additional fees or credit any overpayments as a result of the filing of this paper to Deposit Account No. 02-3978.

Respectfully submitted,

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Date: September 3, 2009

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